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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,505	07/22/2003	Jane Ye	CL001158DIV2	1679
25748	7590	10/31/2005	EXAMINER	
CELERA GENOMICS ATTN: WAYNE MONTGOMERY, VICE PRES, INTEL PROPERTY 45 WEST GUDE DRIVE C2-4#20 ROCKVILLE, MD 20850			JUEDES, AMY E	
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 10/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/623,505	YE ET AL.	
	Examiner	Art Unit	
	Amy E. Juedes, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3, 12, and 24-39 is/are pending in the application.
- 4a) Of the above claim(s) 12 and 24-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3 and 27-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>3/26/04 and 7/8/05</u> | 6) <input checked="" type="checkbox"/> Other: <u>notice to comply</u> |

DETAILED ACTION

1. Applicant's amendment, filed 8/26/05, is acknowledged.

Claims 1-2, 4-11, and 13-23 have been cancelled.
Claims 3 and 12 have been amended.
Claims 24-39 have been added.
Claims 3, 12, and 24-39 are pending.

2. Applicant's election without traverse of group III, in the reply filed on 8/26/05 is acknowledged. During a telephone conversation with Justin Karjala on 10/5/05, an additional provisional election was made without traverse to prosecute only the claims of group III drawn to antibodies (claims 3 and 27-39). Affirmation of this election must be made by Applicant in responding to this Office action.

Claims 12 and 24-26 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claims 3 and 27-39 read on the elected invention and are being acted upon.

3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth herein.

Upon review of the instant application, it is noted that not all of the sequences disclosed in Fig. 2 and 3 are accompanied by SEQ ID Numbers in the drawing or brief description of the drawing. Applicant is reminded of the sequence rules which require a submission for all sequences of more than 10 nucleotides or 4 amino acids (see 37 CFR 1.821-1.825) and is also requested to carefully review the submitted specification for any and all sequences which require compliance with the rules. Applicant is reminded to amend the specification and the claims accordingly.

4. The information disclosures, filed 3/26/04 and 7/8/05, are acknowledged. However, the search report citations (BLAST and European Search) have been lined through, as they have not been

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identified by author, title, publisher, date of publication, and relevant pages, as is required. See MPEP § 609.

5. The abstract of the disclosure is objected to because it does not adequately describe the claimed invention. Correction is required. See MPEP § 608.01(b).

6. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3 and 27-39 are rejected under 35 U.S.C. 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

A) An isolated antibody that selectively binds to a "polypeptide" (Claim 3, 27, 38-39, and dependant claims 28-37).

B) "A composition comprising the antibody...and a pharmaceutically acceptable carrier" (Claims 34-37).

It is noted that applicant has not cited any support for the new claims in the specification. A review of the specification fails to reveal support for the new limitations.

Regarding A), at page 25, the specification discloses "the invention also provides antibodies that selectively bind to one of the peptides of the present invention, a protein comprising such a peptide..." The specification does not appear to disclose antibodies to polypeptides, as now recited in the instant

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claims.

Regarding B), the specification as filed does not appear to provide a written description for the limitation of claims 34-37, where the antibody is part of a composition with a pharmaceutically acceptable carrier.

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3, 27, and 30-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Singer et al.

Singer teaches an antibody specific for a peptide that consists of amino acid residues 406-428 of SEQ ID NO: 2 (see materials and methods). Therefore, said antibody would inherently bind to a polypeptide consisting or comprising SEQ ID NO: 2. Singer also teaches said antibody conjugated to horseradish peroxidase (i.e. a detectable substance).

Thus the reference clearly anticipates the invention.

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 28-29 and 32-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Singer et. al in view of Campbell et. al.

The teachings of Singer are described above.

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Singer does not teach monoclonal antibodies or compositions thereof.

Campbell et. al teaches that monoclonal antibodies are useful for therapeutic, diagnostic, preparative, and basic research purposes (i.e. as compositions in a pharmaceutically acceptable carrier - see pg. 20).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to make a monoclonal antibody as taught by Campbell, to amino acid residues 406-428 of SEQ ID NO: 2, as taught by Singer. Additionally, it would have been obvious to couple said monoclonal antibody to a detectable substance, as taught by Singer. The ordinary artisan at the time the invention was made would have been motivated, and have a reasonable expectation of success, to make a monoclonal antibody to said amino acids, since monoclonal antibodies are powerful immunochemical tools useful for therapeutic purposes, based on their specificity of binding, their homogeneity, and their ability to be produced in unlimited quantities (see Campbell et. al).

11. Claims 38-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Singer et al., in view of Gavilondo et al.

The teachings of Singer are described above.

Singer does not teach an isolated antibody fragment.

Gavilondo teaches that antibody fragments are extremely useful as therapeutic agents due to their smaller size and potentially better tissue penetration and clearance (see pg. 136).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to make an antibody fragment as taught by Gavilondo to amino acid residues 406-428 of SEQ ID NO: 2, as taught by Singer. The ordinary artisan at the time the invention was made would have been motivated to do so, since antibody fragments are extremely useful as therapeutic agents due to their smaller size and potentially better tissue penetration and clearance (see Gavilondo pg. 136). Moreover, one of ordinary skill in the art would have expected to succeed in generating said antibody fragments.

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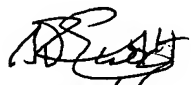
12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E. Juedes, Ph.D. whose telephone number is 571-272-4471. The examiner can normally be reached on 8am - 5pm, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amy E. Juedes, Ph.D.
Patent Examiner
Technology Center 1600
September 15, 2005


10/21/05
G.R. EWOLDT, PH.D.
PRIMARY EXAMINER

Notice to Comply	Application No. 10/623,505	Applicant(s) Ye et al.	
	Examiner Amy E. Juedes, Ph.D.	Art Unit 1644	

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set in the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- ☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).
- ☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- ☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- ☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- ☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- ☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- ☒ 7. Other: Sequences in Figs 2-3 should be identified with SEQ ID NOS.

Applicant Must Provide:

- ☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- ☒ An initial or substitute paper copy of the "Sequence Listing", **as well as an amendment specifically directing its entry into the application.**
- ☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (571) 272-2510

For CRF Submission Help, call (571) 272-2501/2583.

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